Structured Product Labeling (SPL)
High Level Requirements
Document

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TABLE OF CONTENTS

LIST OF FIGURES

Page #

LIST OF TABLES

Page #

1.0 INTRODUCTION

1.1 Purpose of Document

The purpose of this document is to provide vendors with the high level requirements for the Structured Product Labeling (SPL) Project to help them in responding to the request for information.

1.2 Background

The overall purpose of this project is to improve patient safety by ensuring that accurate information about all drug products marketed in the United States is readily available to health care providers, patients, and the public. The project is part of a larger initiative called the DailyMed. The ***DailyMed Initiative*** is a partnership between the FDA, medication manufacturers and distributors, the National Library of Medicine (NLM), and healthcare information suppliers. Here is how it will work.

The pharmaceutical industry, including manufacturers, repackers and relabelers, will collaborate with the FDA to provide ready access to detailed information about their products. This information will be exchanged in a form called Structured Product Labeling (SPL). SPL is a Health Level Seven (HL7) standard, accredited by the American National Standards Institute (ANSI), for exchanging product information. SPL uses extensible mark up language (XML) to electronically tagged information. The information in a SPL file includes the entire content of labeling for the product (e.g., physician labeling for prescription drugs and Drug Facts for over the counter drug products) as well as specifically tagged data elements. The first release of the SPL standard includes XML tagged data elements describing the product (e.g., ingredients, dosage form) and how the product is packaged for distribution (e.g., bottle of 100 tablets). Subsequent releases of SPL will include data elements for other product information. The data elements in the first release of SPL are also submitted by the pharmaceutical industry during the drug inventory process (product listing) required by FDA regulations. See Title 21 of the Code of Federal Regulations, part 207 for information on product listing. The overall SPL project includes procedures involving the process and review of both product labeling and product listing.

Up-to-date SPL for each product will be transmitted from the FDA to the NLM on a daily basis. NLM will provide the SPL, along with other medication information (such as links to publications), in an electronic repository called the DailyMed. Healthcare information suppliers will be able to use the information from this repository to provide providers, patients and the public access to reliable, up-to-date information on the medications they use.

1.3 Objective

The objective of the SPL project is to develop a technical environment that will support processing and managing labeling and listing information necessary to support the DailyMed initiative.

1.4 Scope

The SPL project is limited to the management of the content of labeling changes and product listing. There will be a gradual phase-in of the product types and procedures. The initial phase will include the processing and review of SPL for approved prescription drugs. Other products and product listing procedures will be covered in a subsequent phase(s).

2.0 SPL REVIEW PROCESS

2.1 Introduction

The main objective of the SPL Project is to develop a technical environment that will support processing and managing of SPL. The following sub-sections describe the SPL review process, and a functional concept of the SPL Project.

2.2 SPL Review Process

For the purposes of this document, the SPL Review Process includes the Labeling, Registration, Listing, and Ingredient/UNII Processes.

- Labeling process involves the management of product labeling such as the physician's labeling for prescription drugs and Drug Facts for over the counter drug products.
- Registration process involves companies notifying the FDA of establishments involved in the processing of products.
- Listing process involves companies notifying FDA of products marketed in the United States.
- Ingredient/UNII process involves FDA assigning a unique identifier to an ingredient used in a product.

The above process activities are depicted in Figure 2-1, *SPL Labeling Review Process*, are further described below.

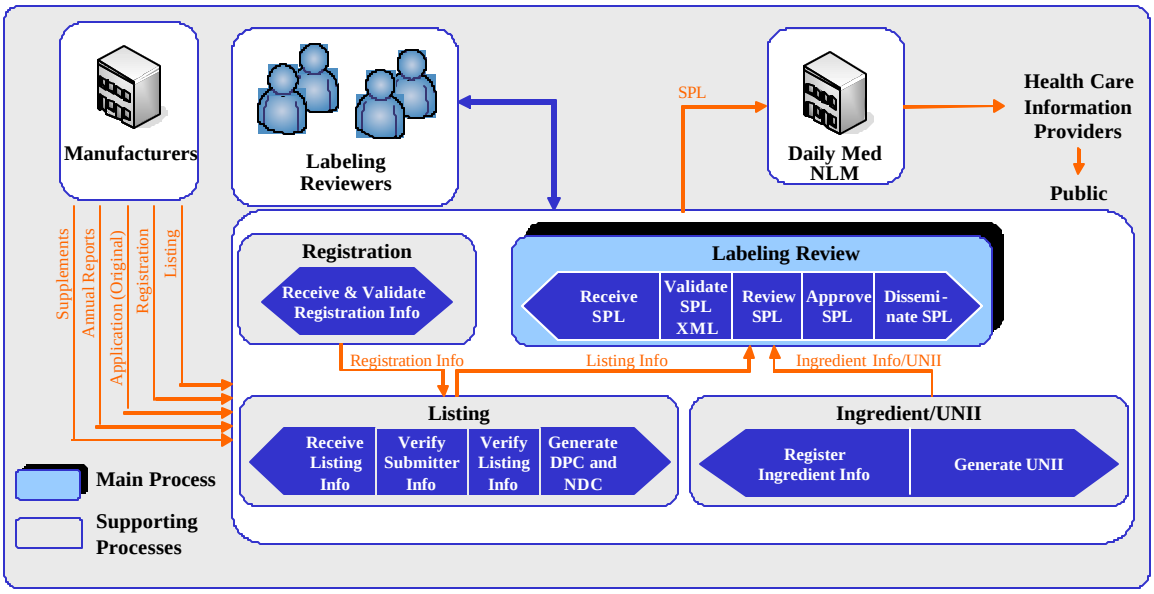

Figure 2-1. SPL Review Process

The **Labeling Review Process** includes the following activities:

- **Receive SPL.** The manufacturers will submit SPL to FDA. These SPL submissions[1] will be in XML format in accordance with the HL7 SPL standards.

- **Validate SPL XML.** After the SPL submission is received, it will be validated. Only valid SPL submissions will be stored in the SPL Repository. The SPL files that do not meet the defined rules for completeness will be rejected and the submitter will be informed about the rejection reason. The validation of SPL XML will be performed by the Labeling System.

- **Review SPL Content.** Ultimate functionality for labeling review by FDA staff may include:
  - Concurrent review of various sections
  - On-line, linked access to various policy and procedure documents (e.g., Code for Federal Regulations, Manuals of Policies and Procedures)
  - Ability to compare different versions of SPL
  - The capability to record results of labeling negotiations conducted outside of the Labeling System.

- **Approve SPL Content.** After review of SPL content, a designated authority will be able to approve SPL content.

- **Transmit SPL.** After final approval, the Labeling System will transmit SPL to the NLM. The SPL dissemination to Health Care information providers and the general public will be performed through the DailyMed.

The **Registration Process** includes the following activity:

- **Receive and Validate Registration Information.** The FDA mandates that manufacturers, repackers and relabelers submit registration information for their establishments. The Registration System receives and stores the registration information.

The **Listing Process** includes the following activities:

- **Receive Listing Information.** The FDA mandates that manufacturers, repackers, and relabelers submit descriptive information (e.g., ingredients, packaging information) for their marketed products for the product listing inventory.

- **Verify Submitter Information.** The Listing System will verify that establishment information has been supplied through the Registration System. If

[1] For this document, the phrase "SPL submissions" refers to the SPL files only. It does not refer to the submission of other documents and data provided with an application.

establishment information has been provided, the listing information will be accepted and stored.

- **Verify Listing Information.** The submitted information will be verified against existing terminology.

- **Manage Product Codes.** Based on the submitted information, product codes will be managed for new listings.

The **Ingredient/UNII Process** includes the following activities:

- **Register Ingredient Information.** FDA will enter identifying information on each ingredient based on defined rules.

- **Generate UNII.** Based on the submitted ingredient information, UNII codes will be generated for new ingredients. The generated codes will be incorporated into SPL.

2.3 SPL Functional Relationship Diagram

A concept of the SPL project is shown on Figure 2-2, *SPL Functional Relationship Diagram*. The diagram depicts the future SPL systems and their interfaces with the existing systems. The initial phase of the project will focus on the Labeling and Ingredient/UNII Systems with the Registration and Listing Systems coming later.

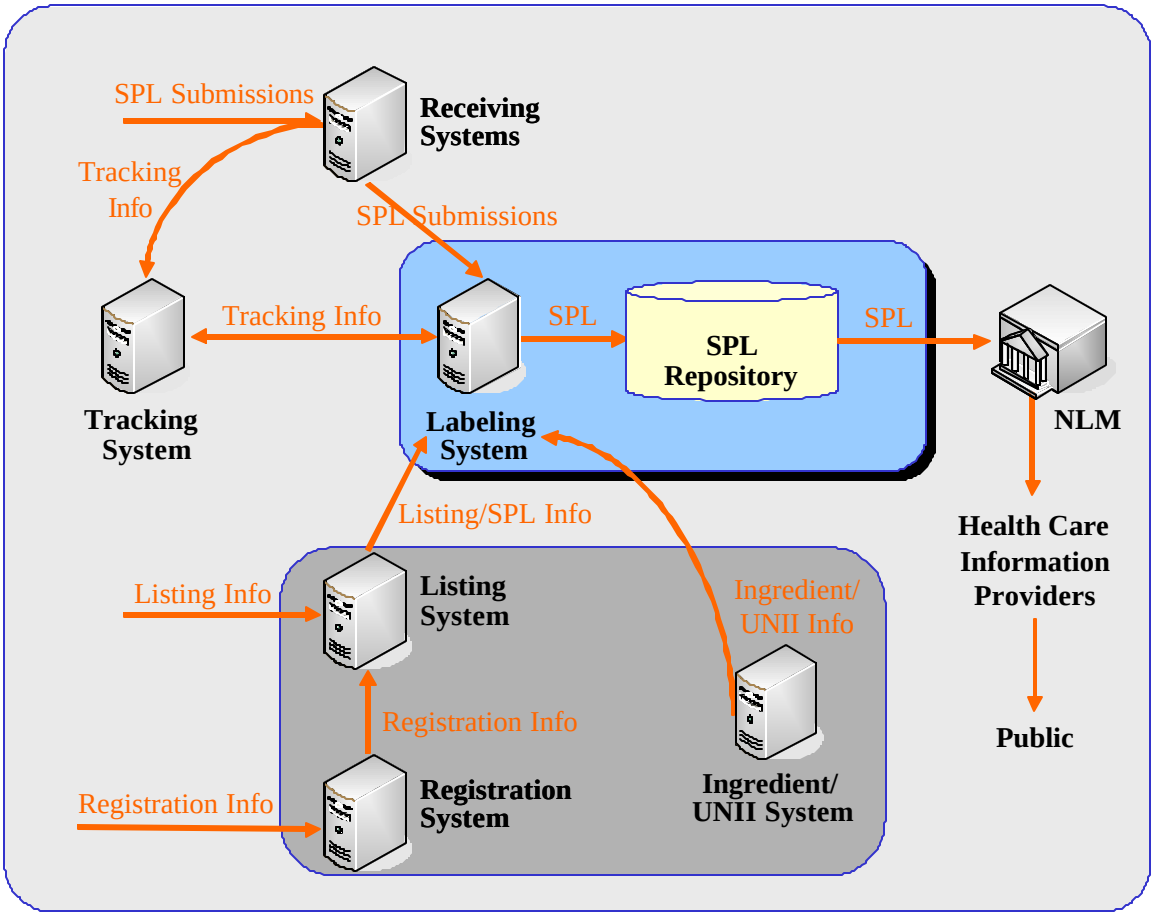

Figure 2-2. SPL Functional Relationship Diagram

All valid SPL submissions received from the manufacturers will be stored in the SPL Repository for processing. The Labeling Review Process will be supported by the Labeling System. In order to facilitate the labeling review process, the system will have interfaces with the following new and existing systems:

- Tracking System for tracking application information associated with new SPL submissions
- Receiving Systems for receipt of incoming SPL submissions
- Listing System for the product listing information
- Ingredient/UNII System for the ingredient/UNII information

All SPL will be transmitted to the central repository (e.g., NLM) for dissemination to the Health Care information suppliers.

The SPL project will be developed and implemented in phases. The SPL functional relationship diagrams for the first two phases of the SPL project are described in Appendix A, *SPL Functional Relationship Diagrams – Phase 1 and Phase 2*.

3.0 SPL FUNCTIONAL AND NON-FUNCTIONAL REQUIREMENTS

3.1 SPL Functional Requirements

The SPL Project constitutes the following systems:

- Labeling System
- Listing System
- Ingredients/UNII System
- Registration System.

The initial phase will not include all the high-level functional requirements for these systems. The details on which requirements are planned for each phase are captured in the subsequent sub-sections and prioritized in Appendix B, *High-Level Requirements Matrix*.

3.1.1 Labeling System Requirements

The Labeling System will enable the Agency to efficiently perform the following functions:

- Receive and validate SPL
- Review and approve SPL
- Generate and maintain audit trail
- Generate reports
- Transmit SPL to NLM.

The high-level requirements for these functional areas are detailed below.

3.1.1.1 Receive and Validate Labeling

The Receive and Validate Labeling function will receive SPL from the Receiving System and validate the SPL submissions. The function will provide the capability to receive SPL and perform validations necessary to ensure compliance with the HL7 SPL standard. The functional requirements are defined in Table 3-1, *Labeling System – Receive and Validate Labeling*.

Table 3-1. Labeling System – Receive and Validate Labeling

Req. ID	Requirement
1.	The system shall provide the capability to receive SPL from the Receiving Systems.
2.	The system shall provide the capability to validate SPL submissions for consistency with terminology according to the HL7 SPL standards (e.g., Code, Structure, and Content).
3.	The system shall provide the capability to store valid SPL along with tracking data (e.g., application number, submission type) in the SPL repository.
4.	The system shall provide the capability to reject invalid SPL submissions.

Table 3-1. Labeling System – Receive and Validate Labeling

Req. ID	Requirement
5.	The system shall provide the capability to notify a Labeling Coordinator about validation results on SPL submissions.
6.	The system shall provide capability to notify a CBE evaluator of SPL with CBE Status.
7.	The system shall provide the capability to generate a notification to the manufacturer detailing the reasons why a SPL submission was rejected.

3.1.1.2 Review and Approve Labeling

The Review and Approve Labeling function will directly aid the steps involved in the SPL review process. The function will provide a comprehensive SPL review capability to the labeling reviewers to ensure efficient and effective labeling review. Note that some of these functions are not planned for the initial phase. The functional requirements are defined in Table 3-2, *Labeling System – Review and Approve Labeling*.

Table 3-2. Labeling System – Review and Approve Labeling

Req. ID	Requirement
1.	The system shall provide the capability to view SPL submissions, including status, section content, XML tagged data elements, and graphics.
2.	The system shall provide the capability to select style-sheets for viewing SPL submissions based on specific labeling reviewer needs.
3.	The system shall provide the capability to review different sections of SPL concurrently.
4.	The system shall provide the capability to prevent multiple users from editing the same section and XML tagged data elements of SPL concurrently.
5.	The system shall provide the capability to search the SPL Repository by any combination of identified search criteria (e.g., status, section, data element).
6.	The system shall provide word processing capability to edit (i.e., add, change, delete) SPL section contents.
7.	The system shall provide the capability to edit (i.e., add, change, delete) XML tagged data elements.
8.	The system shall provide the capability to record comments.
9.	The system shall provide the capability to compare various versions of a SPL section and XML tagged data element highlighting differences (i.e., additions underlined and deletions crossed out).
10.	The system shall provide the capability to compare SPL across the product class.
11.	The system shall provide the capability to validate XML tagged data elements against ingredient information from the Ingredient/UNII System, if applicable.
12.	The system shall provide the capability to validate the XML tagged data elements against standard terminology (e.g., dosage form, route of administration) from reference tables, if applicable.
13.	The system shall provide hyperlinks to reference material (e.g., CFR, MaPPs) pertaining to the section being reviewed.
14.	The system shall provide hyperlinks to the ingredient molecular structures from the Ingredient/UNII System, if applicable.
15.	The system shall provide the capability for the Labeling Coordinator to change the status of one or more sections and XML tagged data elements of SPL to “Approved”.
16.	The system shall provide the capability to generate a notification request to send action letters to manufacturer.
17.	The system shall provide the capability to facilitate a secure method of collaboration between the

Table 3-2. Labeling System – Review and Approve Labeling

Req. ID	Requirement
	FDA reviewers and manufacturer during labeling negotiations.

3.1.1.3 Generate and Maintain Audit Trail

The Audit Trail function will maintain an audit trail of all labeling review activities. The function will track changes, version, status, and date of all SPL submissions and individual sections therein. The function will maintain a history of labeling review actions, including reviewer names, dates, and times. The functional requirements are defined in Table 3-4, *Labeling System – Generate and Maintain Audit Trail*.

Table 3-4. Labeling System – Generate and Maintain Audit Trail

Req. ID	Requirement
1.	The system shall provide the capability to record and maintain version, status, and date of each final SPL section and XML tagged data elements.
2.	The system shall provide the capability to record the final changes (e.g., contents, reviewer, time stamp) made to an SPL section and XML tagged data element.
3.	The system shall provide the capability to record approval decisions and approving authority.
4.	The system shall provide the capability to capture the action letter and link it to the corresponding SPL.

3.1.1.4 Generate Reports

The Reports function addresses the report generation needs of the labeling reviewers. Additionally, the function will generate notification requests to initiate correspondence to manufacturers. The reporting requirements are defined in Table 3-5, *Labeling System – Generate Reports.*

Table 3-5. Labeling System – Generate Reports

Req. ID	Requirement
1.	The system shall provide the capability to generate standard reports using predefined selection criteria (e.g., Status, Section Name, Data Element).
2.	The system shall provide the capability generate reports in multi-sort order.
3.	The systems shall provide the capability to generate reports based on predefined events.
4.	The systems shall provide the capability to generate trend reports.
5.	The system shall provide the capability to generate audit reports.
6.	The system shall provide the capability to generate workflow reports.
7.	The system shall provide the capability to generate a validation result report on SPL submissions.
8.	The system shall provide capability to generate the NLM transmission error report.
9.	The system shall provide capability to generate the system performance statistics reports.
10.	The system shall provide the capability to generate ad hoc reports.

Table 3-5. Labeling System – Generate Reports

Req. ID	Requirement
11.	The system shall provide the capability to generate notification requests.

3.1.1.5 Transmit Approved SPL to NLM

Transmit to NLM function will provide an automated and manual utility for the transmission of approved SPL to NLM. The functional requirements are defined in Table 3-6, *Labeling System – Transmit Approved SPL to NLM*.

Table 3-6. Labeling System – Transmit Approved SPL to NLM

Req. ID	Requirement
1.	The system shall provide the capability to generate approved SPL for transmission, based on defined business rules.
2.	The system shall provide the capability to automatically transmit generated SPL, after a predefined delay period (e.g., 24 hours), to NLM on a specified time schedule.
3.	The system shall provide the capability to track transmission failures.
4.	The system shall provide the capability to notify the system administrator about a transmission failure.
5.	The system shall provide the capability to manually transmit approved SPL.

3.1.1.6 Interfaces

The Labeling System will have interfaces with several systems. The information received through these interfaces will enable the labeling reviewers to process SPL submissions. The interface requirements are defined in Table 3-7, *Labeling System – Interfaces*.

Table 3-7. Labeling System – Interfaces

Req. ID	Requirement
1.	The system shall provide the capability to interface with the Tracking System (e.g., COMIS/DARRTS) for tracking information (e.g., application number, submission type, submission status).
2.	The system shall provide the capability to interface with the Receiving System (e.g., EDR) for receipt of incoming SPL submissions.
3.	The system shall provide the capability to interface with the Ingredient/UNII System for the ingredient/UNII information, if applicable.
4.	The system shall provide the capability to interface with the Listing System for listing information and SPL submissions.

3.1.2 Listing System Requirements

The Listing System will enable the FDA personnel to efficiently perform the following listing functions:

- Receive and validate listing information
- Process listing information
- Generate reports.

The high-level requirements for these functional areas are captured in the subsequent sub-sections.

3.1.2.1 Receive and Validate Listing Information

The Receive and Validate Listing Information function will enable the receiving and validation of listing information and associated files from the manufacturers, repackers, and relabelers. The functional requirements are defined in Table 3-8, *Listing System – Receive and Validate Listing Information*.

Table 3-8. Listing System – Receive and Validate Listing Information

Req. ID	Requirement
1.	The system shall provide the capability to receive listing information from the manufacturer, repacker and relabeler
2.	The system shall provide the capability to receive the SPL submissions from the manufacturer.
3.	The system shall provide the capability to validate the received listing information.
4.	The system shall provide the capability to verify the manufacturer, repacker and relabeler information against the registration information from the Registration System.
5.	The system shall provide the capability for manufacturer, repacker, and relabeler to view and update the listing information and reviewer to provide quality control.
6.	The system shall provide the capability to store the listing information.

3.1.2.2 Process Listing Information

The Process Listing Information function will manage product code information. The functional requirements are defined in Table 3-9, *Listing System – Process Listing Information*.

Table 3-9. Listing System – Process Listing Information

Req. ID	Requirement
1.	The system shall provide the capability to merge information collected in the labeling and listing system.
2.	The system shall provide the capability to manage Product Codes.
3.	The system shall provide the capability to store Product Codes.
4.	The system shall provide the capability to exchange Product Codes with manufacturer, repacker and relabeler.

3.1.2.3 Generate Reports

The Reports function will enable the FDA staff to generate standard and ad hoc reports. Additionally, the function will generate notification requests to initiate correspondence to manufacturers. The reporting requirements are defined in Table 3-10, *Listing System – Generate Reports.*

Table 3-10. Listing System – Generate Reports

Req. ID	Requirement
1.	The system shall provide the capability to generate standard reports using predefined selection criteria (e.g., manufacturer, product name).
2.	The system shall provide the capability to generate ad hoc reports.
3.	The system shall provide the capability to generate notification requests.

3.1.2.4 Interfaces

To facilitate the processing of SPL submissions, the Listing System will have interfaces with several systems. The interface requirements are defined in Table 3-11, *Listing System – Interfaces*.

Table 3-11. Listing System – Interfaces

Req. ID	Requirement
1.	The system shall provide the capability to interface with the Labeling System to retrieve SPL information.
2.	The system shall provide the capability to interface with the Labeling System to merge data.
3.	The system shall provide the capability to interface with the Registration System for the manufacturer, repacker and relabeler registration information.

3.1.3 Ingredients/UNII System Requirements

The Ingredients/UNII System will enable the FDA users to efficiently perform the following functions:

- Register and validate ingredient information
- Generate UNII
- Search for matching structure/UNII using predefined selection criteria
- Generate standard reports.

The system requirements (*) are defined in Table 3-12, *Ingredients/UNII System*.

(*) – FDA is currently using the Subsistence Registration System (SRS) that performs the above functions. FDA may decide to use this system instead of developing a new one. In this case, only an interface from Labeling System to the existing SRS will be required (see Table 3-7, Requirement 3).

Table 3-12. Ingredients/UNII System

Req. ID	Requirement
1.	The system shall provide the capability to register ingredient information.
2.	The system shall provide the capability to store the ingredient information (e.g., name, structure).
3.	The system shall provide the capability to generate UNII code for ingredients.
4.	The system shall provide the capability to search for matching structure or UNII code using any combination of identified selection criteria (e.g., BDNUM, compound name).
5.	The system shall provide the capability to restrict changes to the ingredient information after the UNII is generated for the ingredient.
6.	The system shall provide the capability to register new compound defined as single structure and mixed structures.
7.	The system shall provide the capability to update compound data (e.g., BDNUM, Name).
8.	The system shall provide the capability to generate standard reports using predefined selection criteria (e.g., ingredient name, BDNUM).
9.	The system shall provide the capability to interface with the Ingredient Dictionary for ingredient information.

3.1.4 Registration System Requirements

The Registration System will enable the FDA users to efficiently perform the following functions:

- Receive and validate registration information
- Generate registration number
- Generate standard reports.

The system requirements are defined in Table 3-13, *Registration System*.

Table 3-13. Registration System

Req. ID	Requirement
1.	The system shall provide the capability to receive registration information from the manufacturer/repacker/relabeler.
2.	The system shall provide the capability to validate registration information.
3.	The system shall provide the capability to store the registration information.
4.	The system shall provide the capability to generate the registration number for each site being registered.
5.	The system shall provide the capability to send/print a notification request for communicating the registration number to the manufacturer/repacker/relabeler.
6.	The system shall provide the capability to generate standard reports using predefined selection criteria.

Table 3-13. Registration System

Req. ID	Requirement
7.	The system shall provide the capability to automatically send a notification request informing the manufacturer/repacker/relabeler to submit registration updates.

3.2 SPL Non-Functional Requirements

The high-level non-functional requirements for the SPL Project will help ensure the efficient operation of the systems involved in the SPL Project. The requirements outline the performance, administration, security, and environmental needs of the SPL Project.

The high-level non-functional requirements are captured in the subsequent sub-sections and prioritized in Appendix B, *High-Level Requirements Matrix*.

3.2.1 Performance and Availability Requirements

The performance and availability requirements specify the maximum numbers of transactions, storage requirements, concurrent users, availability, or any other quantifiable information about performance requirements placed on the SPL Project. The requirements are defined in Table 3-14, *Performance and Availability.*

Table 3-14. Performance and Availability

Req. ID	Requirement
1.	The system shall support 5,000 users.
2.	The system shall provide response to the user in less than 10 seconds (excluding reports) if less than 1,000 concurrent users are logged in.
3.	The system shall provide response to the user in less than 15 seconds (excluding reports) if more than 1,000 concurrent users are logged in.
4.	The system shall provide the capability to process and store at least 1,000 original SPL per year for the next 10 years.
5.	The system shall provide capability to process and store at least 15,000 SPL changes (labeling supplements and annual reports) per year for the next 10 years.
6.	The system shall provide the capability to generate performance statistics for a given period of time.
7.	The system shall be available to authorized internal users at all FDA geographical locations.
8.	The system shall be available to authorized external users via the Internet.
9.	The system shall be available to all authorized (internal and external) users 95 % of time during official business hours, excluding scheduled maintenance.

3.2.2 System Administration Requirements

The system administration requirements provide the authorized system administration staff with a comprehensive means to maintain and administer the SPL Project systems. The requirements are defined in Table 3-15, *System Administration*.

Table 3-15. System Administration

Req. ID	Requirement
1.	The system shall provide the capability to create and maintain user roles and profiles.
2.	The system shall provide the capability to remove user privileges/accounts.
3.	The system shall provide the capability to perform database backups and restores.
4.	The system shall provide the capability to create and maintain online help files.
5.	The system shall provide the capability to create and maintain look up tables.
6.	The system shall provide the capability to update hyperlinks to supporting documentation.
7.	The systems shall provide the capability to archive old SPL versions.
8.	The system shall provide the capability to perform global changes across a product class.
9.	The system shall provide the capability to retract/withdraw approved SPL from the SPL Repository due to human error.

3.2.3 System Security Requirements

The system security requirements address login, role based security, and other security related needs for the SPL Project. The requirements are defined in Table 3-16, *System Security.*

Table 3-16. System Security

Req. ID	Requirement
1.	The system shall comply with FDA security policies and procedures.
2.	The system shall provide the capability to implement role-based security.
3.	The system shall provide the capability to integrate with FDA's single sign on security solution if applicable.
4.	The system shall authenticate users upon sign on.
5.	The system shall provide users with functional and data access based on the roles assigned to their profiles.
6.	The system shall provide the capability to integrate with FDA's firewall solution for secured access via the Internet.
7.	The system shall encrypt sensitive communications over the FDA Intranet/Internet.
8.	The system shall have the capability to automatically alert the system administration staff if an unauthorized access occurs.
9.	The system shall provide the capability to integrate with FDA's virus protection software.

3.2.4 System Environment Requirements

The system environment requirements pertain to the SPL technical environment and support the design and development of the project. The requirements are defined in Table 3-17, *System Environment*.

Table 3-17. System Environment

Req. ID	Requirement

Table 3-17. System Environment

Req. ID	Requirement
1.	The system shall be compliant with FDA's Enterprise Architecture.
2.	The system shall be compatible with the prevailing versions of Web browsers used by FDA.
3.	The system shall store data into a relational and/or XML database.

3.2.5 Section 508 Requirements

Section 508 requires that Federal agencies' electronic and information technology is accessible to people with disabilities. The Section 508 requirements pertain to Section 508 compliance. The requirements are defined in Table 3-18, *Section 508*.

Table 3-18. Section 508

Req. ID	Requirement
1.	The system shall be compliant with Section 508 requirements.

3.2.6 Additional Requirements

The additional requirements provide supplementary requirements that are relevant to the SPL Project. The requirements are defined in Table 3-19, *Additional Requirements.*

Table 3-19 Additional Requirements

Req. ID	Requirement
1.	The system shall provide context specific online help on the system functions.
2.	The system shall provide the facility to log and report application errors/failure.
3.	The system shall be scalable to accommodate increased workload in the future.
4.	The system shall comply with the Federal Information Processing Standards Publications (FIPS PUBS) outlined in Appendix C, Table C-1 FIPS PUBS.

APPENDIX A

SPL Functional Relationship Diagrams – Phase 1 and Phase 2

SPL Functional Relationship Diagrams – Phase 1 and Phase 2

The SPL project will be developed and implemented in phases. The SPL functional relationship diagrams are pictorial depictions of the first two phases of the SPL project. The diagrams include current and emerging systems and present how these systems will support the labeling review process.

The first two phases of the SPL Project include drug products covered under product listing regulations. The future phases of the SPL Project may concentrate on other FDA regulated products such as dietary supplements and medical devices.

SPL Project Phase 1

The goal of the SPL Project Phase 1 is to create a system for SPL submissions for approved prescription drugs. The new systems will be integrated with the existing systems as shown on Figure A-1, *SPL Project Phase 1*.

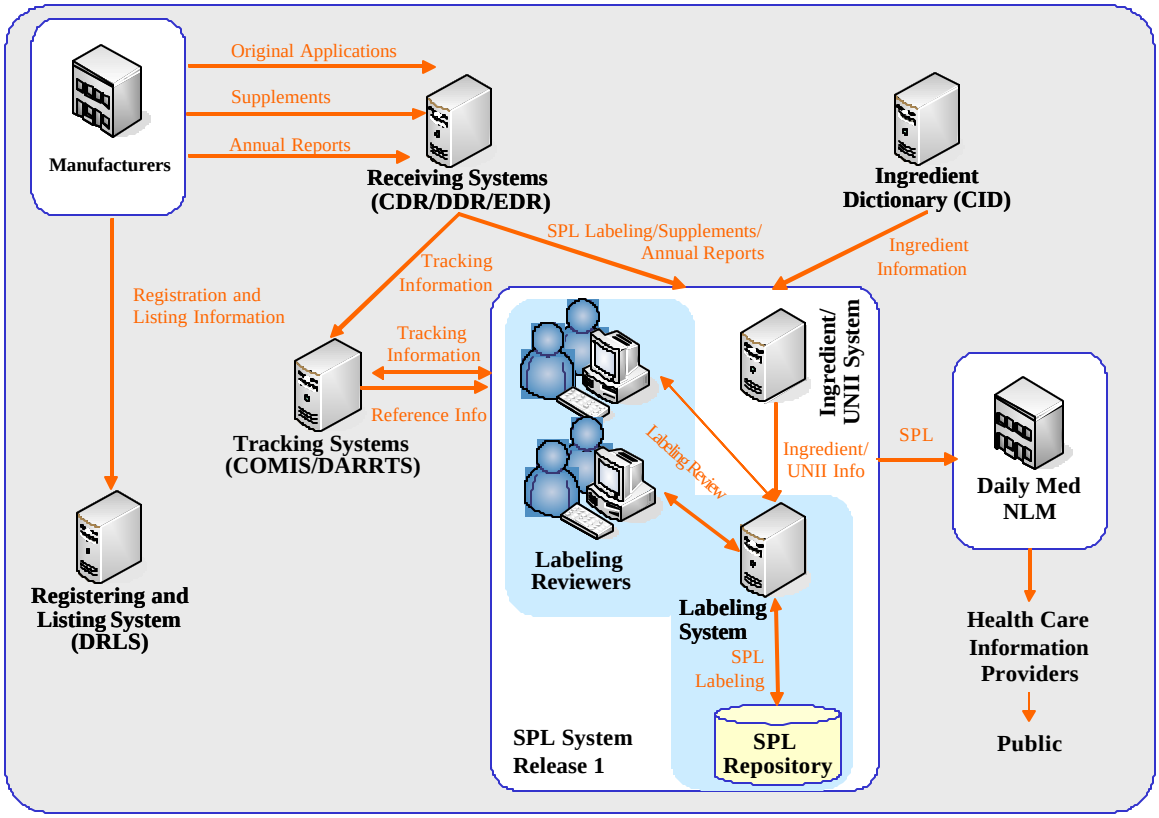

Figure A-1. SPL Project Phase 1

The Figure A-1 illustrates the SPL Project at the end of Phase 1. The figure shows the relationship between the key stakeholders and new and existing systems and the flow of information from the applicant to the NLM. The key stakeholders directly associated with the SPL Project Phase 1 are FDA, manufacturers, NLM, health care information suppliers and the public.

Table A-1, *SPL Project Phase 1 Systems*, provides a description of the systems shown in Figure A-1 that will support the labeling review process.

Table A-1. SPL Project Phase 1 Systems

No.	Name	Description
	SPL Project Systems	
1.	Labeling System	The labeling reviewers will use the Labeling System to receive, review, approve, and transmit SPL. The system will also maintain the SPL Repository.
2.	Ingredient/UNII System	The Ingredient/UNII System will be used to generate and maintain UNII for product ingredients. It will store the ingredient information such as names, structures, and definitions. The system will interface with the Ingredient Dictionaries to provide other ingredient related information required by the labeling review process.
	Other Supporting Systems	
1.	Receiving Systems	The Receiving Systems will be used for receiving the SPL submissions (including original SPL and SPL supplements). The systems will also generate the original tracking information for all submissions. The Receiving Systems will act as the staging area before the Labeling System pulls the SPL submissions for review and processing. For the approved prescription drug SPL, the Receiving Systems will be Central Document Room (CDR) and Electronic Document Room (EDR).
2.	Tracking System	The Tracking System will be used to track the SPL submissions. The system will interface with the Labeling System to provide the tracking information upon arrival of a SPL submission. For the approved prescription drug SPLs, the Tracking System will be the Center-wide Oracle Management Information System (COMIS) and the Document Archiving, Reporting, and Regulatory Tracking System (DARRTS).
3.	Registration and Listing System	The Registration and Listing System will be used to receive and store the registration and listing information from the manufacturers, repackers and relabelers. For the approved prescription drug SPL, the Registration and Listing System will be the existing Drug Registration and Registration System (DRLS).
4.	Ingredient Dictionaries	The Ingredient Dictionaries will be used to store ingredient information. The system will interface with the Ingredient/UNII System to provide detailed ingredient information. For the approved prescription drug SPL, the Ingredient Dictionary will be the Chemistry Ingredient Dictionary (CID).

As depicted on Figure A-1, the manufacturers will send SPL submissions, including original SPL and SPL supplements, to FDA for approved prescription drugs. The SPL submissions will be received and stored in the Electronic Repository using the Receiving Systems. Also, tracking information including a unique submission identifier, application number, submission type, and submission status will be created in the Tracking System. Based on this information, the Labeling System will retrieve the SPL submissions into the SPL Repository for review and processing by the labeling reviewers. The labeling reviewers will view SPL using the Labeling System. The system will facilitate the labeling review process by interfacing with other supporting systems to pull the following information:

- Ingredient/UNII information from the Ingredient/UNII System
- Reference information from the Tracking System

Once the labeling review is complete, the approved SPL will be transmitted to NLM for dissemination to healthcare information suppliers and public.

SPL Project Phase 2

The goals of the SPL Project Phase 2 are:

- Cover other drug listing products including unapproved prescription drugs and OTC drugs
- Develop systems that will process drug listing information
- Manage product codes
- Register information about manufacturers, repackers, and relabelers.

The new systems will be integrated with the existing systems as it is shown in Figure A-2, *SPL Project Phase 2*.

The Figure A-2, *SPL Project Phase 2*, illustrates the SPL Project at the end of Phase 2. The figure shows the relationship between the key stakeholders and new and existing systems and the flow of information from the companies (e.g., manufacturers, repackers, and relabelers) to the recipients (e.g., healthcare community/public). The key stakeholders directly associated with the SPL Project Phase 2 are the same as Phase 1.

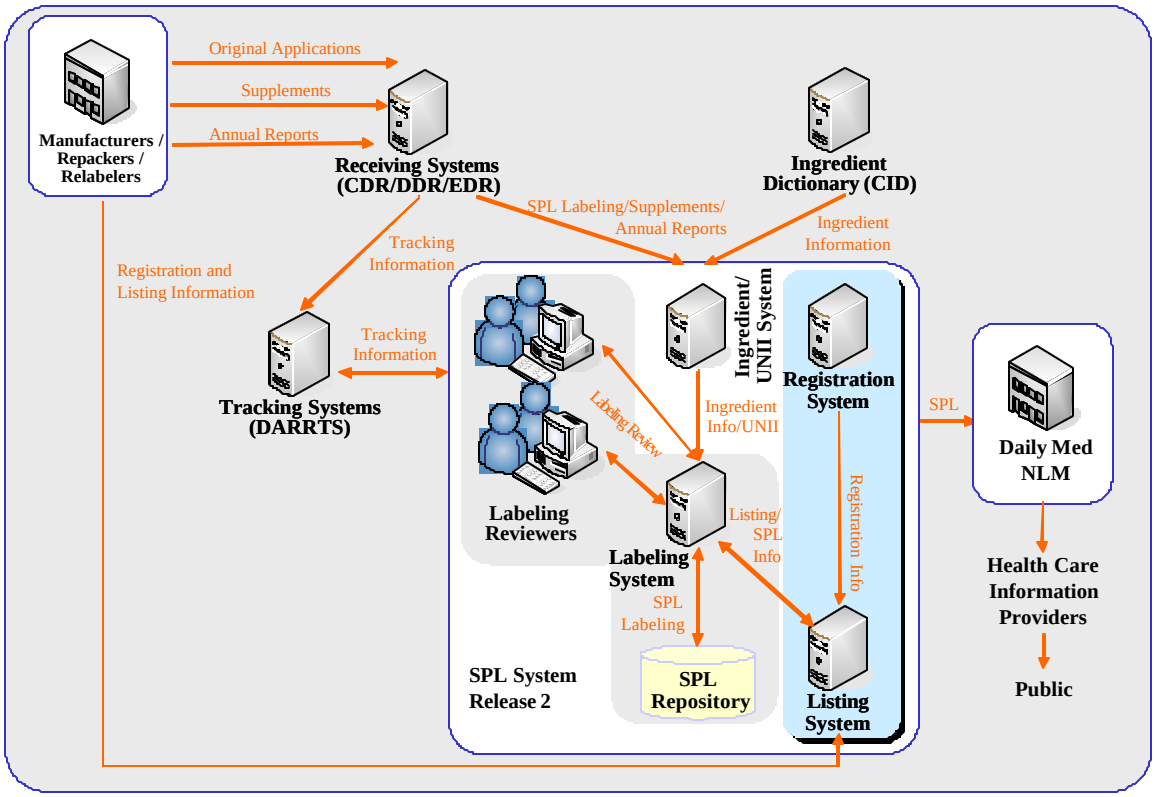

Figure A-2. SPL Project Phase 2

Table A-2, *SPL Project Phase 2 Systems*, provides a description of the systems, as shown in Figure A-2, *SPL Project Phase 2*, that will support the labeling review process.

Table A-2. SPL Project Phase 2 Systems

No.	Name	Description
	SPL Systems	
1.	Labeling System	The labeling reviewers will use the Labeling System to receive, review, approve, and transmit SPL. The system will also maintain the SPL Repository.
2.	Ingredient/UNII System	The Ingredient/UNII System will be used to generate and maintain UNII for product ingredients. It will store the ingredient information such as names, structures, and definitions. The system will interface with the Ingredient Dictionaries to provide other ingredient related information required by the labeling review process.
3.	Listing System	The Listing System will be used to receive and store the listing information from the manufacturers, repackers, and relabelers. The system will interface with the Labeling System to pass received information.

Table A-2. SPL Project Phase 2 Systems

No.	Name	Description
4.	Registration System	The Registration System will be used to receive and store the registration information from the manufacturers, repackers, and relabelers. The system will interface with the Listing System to provide registration information.
	Other Supporting Systems	
1.	Receiving Systems	The Receiving Systems will be used for receiving the SPL submissions (including original labeling with applications, labeling changes, and labeling changes with annual reports). The systems will also generate the original tracking information for all submissions. The Receiving Systems will act as the staging area before the Labeling System pulls the SPL submissions for review and processing. For the drug products, the Receiving Systems will be CDR and EDR.
2.	Tracking System	The Tracking System will be used to track the SPL submissions. The system will interface with Labeling System to provide the tracking information upon arrival of a SPL submission. For the drug products, the Tracking System will be DARRTS.
3.	Ingredient Dictionaries	The Ingredient Dictionaries will be used to store ingredient information. The system will interface with the Ingredient/UNII System to provide detailed ingredient information. For the drug products, Ingredient Dictionary will be CID.

As depicted in Figure A-2, *SPL Project Phase 2*, the manufacturers of drugs listing products may pass SPL submissions through the Listing System. The SPL submissions will be stored in the SPL Repository. The system will facilitate the labeling review process by interfacing with other supporting systems to pull the following information:

- Ingredient/UNII information from the Ingredient/UNII System
- Reference table information from the Tracking System
- SPL submissions from the Listing System.

Once the listing is completed, the SPL is transmitted to the NLM for dissemination.

APPENDIX B

High-Level Requirements Prioritization Matrix

Release 1A: This release will constitute the development and implementation of Labeling System and Ingredient/UNII System. For the Labeling System the intention is to implement core labeling review capabilities for prescription drugs. The core capabilities for both systems include the following:

- Receive and Validate Labeling
- Approve Labeling
- Audit Trail
- Transmit to NLM
- Interfaces with other systems
- Receive and validate ingredient information
- Generate UNII.

Release 1B: This release will enhance the functionality of the Labeling System and Ingredient/UNII System to include the following:

- Enhanced review capabilities
- Report generation capabilities.

Release 2: This release will extend the functionality of the Labeling System implemented in earlier releases to include all drug listing products same question regulated. Additionally, this release will also constitute the development and implementation of Listing System and Registration System. The implementation of these two systems will automate the following:

- Drug listing process
- Establishment registration process.

Subsequent Releases: Subsequent releases will extend the functionality of the SPL Project systems to process labeling for other FDA regulated products such as dietary supplements, and medical devices.

Table B-1, *SPL Project Functional Requirements Prioritization Matrix*, presents the high level functional requirements and maps them to the releases (e.g., 1A, 1B, 2) they will be implemented. Table B-1 also identifies if the requirement is essential (Column "E") to the labeling review process.

Table B-1. SPL Project Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
3.1.1 Labeling System					
3.1.1.1 Receive and Validate Labeling					

Table B-1. SPL Project Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
1.	The system shall provide the capability to receive all SPL submissions (e.g., Original, Supplements).	✓	✓		
2.	The system shall provide the capability to validate SPL submissions for consistency with terminology according to the HL7 SPL standards (e.g., Code, Structure, and Content).	✓	✓		
3.	The system shall provide the capability to store valid SPL submissions (e.g., original submissions, supplements, annual reports) along with their tracking data (e.g., application number, submission type) in the SPL repository.	✓	✓		
4.	The system shall provide the capability to reject invalid SPL submissions.	✓	✓		
5.	The system shall provide the capability to notify a Labeling Coordinator about validation results on SPL submissions.	✓	✓		
6.	The system shall provide capability to notify a CBE evaluator of SPL with CBE Status.	✓	✓		
7.	The system shall provide the capability to generate a notification to the manufacturer detailing the reasons why a SPL submission was rejected.				✓
3.1.1.2 Review and Approve Labeling					
1.	The system shall provide the capability to view SPL submissions, including status, section content, XML tagged data elements, and graphics.	✓	✓		
2.	The system shall provide the capability to select style-sheets for viewing SPL submissions based on specific labeling reviewer needs.		✓		
3.	The system shall provide the capability to review different sections of SPL concurrently.	✓	✓		
4.	The system shall provide the capability to prevent multiple users from editing the same section and XML tagged data elements of SPL concurrently.	✓	✓		
5.	The system shall provide the capability to search the SPL Repository by any combination of identified search criteria (e.g., status, section, data element).	✓	✓		
6.	The system shall provide word processing capability to edit (i.e., add, change, delete) SPL section contents.	✓	✓		
7.	The system shall provide the capability to edit (i.e., add, change, delete) XML tagged data elements.	✓	✓		
8.	The system shall provide the capability to record comments.			✓	
9.	The system shall provide the capability to compare various versions of a SPL section and XML tagged data element highlighting differences (i.e., additions underlined and deletions crossed out).	✓	✓		
10.	The system shall provide the capability to compare SPL across the product class.				✓
11.	The system shall provide the capability to validate XML tagged data elements against ingredient information from the Ingredient/UNII System, if applicable.		✓		
12.	The system shall provide the capability to validate the XML tagged data elements against standard terminology (e.g., dosage form, route of administration) from reference tables, if applicable.		✓		
13.	The system shall provide hyperlinks to reference material (e.g., CFR, MaPPs) pertaining to the section being reviewed.			✓	
14.	The system shall provide hyperlinks to the ingredient molecular structures from the Ingredient/UNII System, if applicable.			✓	
15.	The system shall provide the capability to change the status of one or more sections and XML tagged data elements of SPL to “Approved” by the Labeling Coordinator.	✓	✓		

Table B-1. SPL Project Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
16.	The system shall provide the capability to generate a notification request to send action letters to manufacturer.			✓	
17.	The system shall provide the capability to facilitate a secure method of collaboration between the FDA reviewers and manufacturers during labeling negotiations.				✓
3.1.1.3 Generate and Maintain Audit Trail					
1.	The system shall provide the capability to record and maintain version, status, and date of each final SPL section and XML tagged data elements.	✓	✓		
2.	The system shall provide the capability to record the final changes (e.g., contents, reviewer, time stamp) made to an SPL section and XML tagged data element.	✓	✓		
3.	The system shall provide the capability to record approval decisions and approving authority.	✓	✓		
4.	The system shall provide the capability to capture the action letter and link it to the corresponding SPL.			✓	
3.1.1.4 Generate Reports					
1.	The system shall provide the capability to generate standard reports using predefined selection criteria (e.g., Status, Section Name, and Data Element).			✓	
2.	The system shall provide the capability generate reports in multi-sort order.			✓	
3.	The systems shall provide the capability to generate reports based on predefined events.			✓	
4.	The systems shall provide the capability to generate trend reports.			✓	
5.	The system shall provide the capability to generate audit reports.			✓	
6.	The system shall provide the capability to generate workflow reports.			✓	
7.	The system shall provide the capability to generate a validation result report on SPL submissions.	✓	✓		
8.	The system shall provide capability to generate the NLM transmission error report.	✓	✓		
9.	The system shall provide capability to generate the system performance statistics reports.				✓
10.	The system shall provide the capability to generate ad hoc reports.			✓	
11.	The system shall provide the capability to generate notification requests.			✓	
3.1.1.5 Transmit Approved SPL to NLM					
1.	The system shall provide the capability to generate SPL for transmission, based on defined business rules.	✓	✓		
2.	The system shall provide the capability to automatically transmit generated SPLs, after a predefined delay period (e.g., 24 hours), to NLM on a specified time schedule.	✓	✓		
3.	The system shall provide the capability to track transmission failures.	✓	✓		
4.	The system shall provide the capability to notify the system administrator about a transmission failure.	✓	✓		
5.	The system shall provide the capability to manually transmit approved SPL.	✓	✓		
3.1.1.6 Interfaces					
1.	The system shall provide the capability to interface with the Tracking System (e.g., COMIS/DARRTS) for tracking information (e.g., application number, submission type, submission status).		✓		
2.	The system shall provide the capability to interface with the Receiving System (e.g., EDR) for receipt of incoming SPL submissions.	✓	✓		

Table B-1. SPL Project Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
3.	The system shall provide the capability to interface with the Ingredient/UNII System for the ingredient/UNII information, if applicable.		✓		
4.	The system shall provide the capability to interface with the Listing System for listing information and SPL submissions.				✓
3.1.2 Listing System					
3.1.2.1 Receive and Validate Listing Information					
1.	The system shall provide the capability to receive listing information from the manufacturer/repacker/relabeler.	✓			✓
2.	The system shall provide the capability to receive the SPL submissions from the manufacturer.	✓			✓
3.	The system shall provide the capability to validate the received listing information.	✓			✓
4.	The system shall provide the capability to verify the manufacturer, repacker and relabeler information against the registration information from the Registration System.				✓
5.	The system shall provide the capability for manufacturer, repacker, and relabeler to view and update the listing information and the reviewer to provide quality control.	✓			✓
6.	The system shall provide the capability to store the listing information.	✓			✓
3.1.2.2 Process Listing Information					
1.	The system shall provide the capability to merge information collected in the labeling and listing system.	✓			✓
2.	The system shall provide the capability to manage Product Code.	✓			✓
3.	The system shall provide the capability to store Product Codes.	✓			✓
4.	The system shall provide the capability to exchange Product Codes with manufacturer, repacker and relabeler.	✓			✓
3.1.2.3 Generate Reports					
1.	The system shall provide the capability to generate standard reports using predefined selection criteria (e.g., manufacturer, product name).				✓
2.	The system shall provide the capability to generate ad hoc reports.				✓
3.	The system shall provide the capability to generate notification requests.				✓
3.1.2.4 Interfaces					
1.	The system shall provide the capability to interface with the Labeling System to retrieve SPL information.	✓			✓
2.	The system shall provide the capability to interface with the Labeling System to merge data.	✓			✓
3.	The system shall provide the capability to interface with the Registration System for the manufacturer, repacker and relabeler registration information.				✓
3.1.3 Ingredients/UNII System					
1.	The system shall provide the capability to register ingredient information.	✓	✓		
2.	The system shall provide the capability to store the ingredient information (e.g., name, structure).	✓	✓		
3.	The system shall provide the capability to generate UNII code for ingredients.	✓	✓		
4.	The system shall provide the capability to search for matching structure or UNII code using any combination of identified selection criteria (e.g., BDNUM, compound name).	✓	✓		
5.	The system shall provide the capability to restrict changes to the ingredient information after the UNII is generated for the ingredient.	✓	✓		

Table B-1. SPL Project Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
6.	The system shall provide the capability to register new compound defined as single structure and mixed structures.	✓	✓		
7.	The system shall provide the capability to update compound data (e.g., BDNUM, Name).	✓	✓		
8.	The system shall provide the capability to generate standard reports using predefined selection criteria (e.g., ingredient name, BDNUM).			✓	
9.	The system shall provide the capability to interface with the Ingredient Dictionary for ingredient information.	✓	✓		
3.1.4 Registration System					
1.	The system shall provide the capability to receive registration information from the manufacturer/repacker/relabeler.	✓			✓
2.	The system shall provide the capability to validate registration information.	✓			✓
3.	The system shall provide the capability to store the registration information.	✓			✓
4.	The system shall provide the capability to generate the registration number for each site being registered.	✓			✓
5.	The system shall provide the capability to send/print a notification request for communicating the registration number to the manufacturer/ repacker/relabeler.	✓			✓
6.	The system shall provide the capability to generate standard reports using predefined selection criteria.				✓
7.	The system shall provide the capability to automatically send a notification request informing the manufacturer/repacker/relabeler to submit registration updates.				✓

E – Essential; 1A – Release 1A; 1B – Release 1B; 2 – Release 2

Table B-2, *SPL Project Non-Functional Requirements Prioritization Matrix* presents the high level non-functional requirements and maps them to the releases (i.e., 1A, 1B, 2) they will be implemented. Table B-1 also identifies if the requirement is essential (Column "E") to the labeling review process.

Table B-2. SPL Project Non-Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
3.2.1 Performance and Availability Requirements					
1.	The system shall support 5,000 users.		✓		
2.	The system shall provide response to the user in less than 10 seconds (excluding reports), if less than 1,000 concurrent users are logged in.	✓	✓		
3.	The system shall provide response to the user in less than 15 seconds (excluding reports), if more than 1,000 concurrent users are logged in.	✓	✓		
4.	The system shall provide the capability to process and store at least 1,000 original SPLs per year for the next 10 years.		✓		✓
5.	The system shall provide capability to process and store at least 15,000 SPL changes (labeling supplements and annual reports) per year for the next 10 years.		✓		✓
6.	The system shall provide the capability to generate performance statistics for a				✓

Table B-2. SPL Project Non-Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
	given period of time.				
7.	The system shall be available to authorized internal users at all FDA geographical locations.	✓	✓		✓
8.	The system shall be available to authorized external users via the Internet.				✓
9.	The system shall be available to all authorized (internal and external) users 95 % of time during official business hours, excluding scheduled maintenance.	✓	✓		✓
3.2.2 System Administration Requirements					
1.	The system shall provide the capability to create and maintain user roles and profiles.	✓	✓		
2.	The system shall provide the capability to remove user privileges/accounts.	✓	✓		
3.	The system shall provide the capability to perform database backups and restores.	✓	✓		
4.	The system shall provide the capability to create and maintain online help files.	✓	✓	✓	✓
5.	The system shall provide the capability to create and maintain look up tables.	✓	✓	✓	✓
6.	The system shall provide the capability to update hyperlinks to supporting documentation.	✓	✓	✓	✓
7.	The systems shall provide the capability to archive old SPL versions.			✓	
8.	The system shall provide the capability to perform global changes across a product class.			✓	✓
9.	The system shall provide the capability to retract/withdraw approved SPL from the SPL Repository due to human error.	✓	✓		
3.2.3 System Security Requirements					
1.	The system shall comply with FDA security policies and procedures.	✓	✓		
2.	The system shall provide the capability to implement role-based security.	✓	✓		
3.	The system shall provide the capability to integrate with FDA's single sign on security solution, if applicable.		✓	✓	✓
4.	The system shall authenticate users upon sign on.	✓	✓		
5.	The system shall provide users with functional and data access based on the roles assigned to their profiles.	✓	✓	✓	✓
6.	The system shall provide the capability to integrate with FDA's firewall solution for secured access via the Internet.	✓			✓
7.	The system shall encrypt sensitive communications over the FDA Intranet/Internet.				✓
8.	The system shall have the capability to automatically alert the system administration staff if an unauthorized access occurs.				✓
9.	The system shall provide the capability to integrate with FDA's virus protection software.	✓	✓		
3.2.4 System Environment Requirements					
1.	The system shall be compliant with FDA's Enterprise Architecture.	✓	✓		✓
2.	The system shall be compatible with the prevailing versions of Web browsers used by FDA.	✓	✓		✓
3.	The system shall store data into a relational and/or XML database.	✓	✓		✓
3.2.5 Section 508 Requirements					
1.	The system shall be compliant with Section 508 requirements.	✓	✓	✓	✓
3.2.6 Additional Requirements					
1.	The system shall provide context specific online help on the system functions.	✓	✓	✓	✓
2.	The system shall provide the facility to log and report application errors/failure.				✓
3.	The system shall be scalable to accommodate increased workload in the future.		✓	✓	✓

Table B-2. SPL Project Non-Functional Requirements Prioritization Matrix

Req. ID	Requirements	E	1 A	1 B	2
4.	The system shall comply with the Federal Information Processing Standards Publications (FIPS PUBS) outlined in Appendix C, Table C-1 FIPS PUBS.		✓	✓	✓

E – Essential; 1A – Release 1A; 1B – Release 1B; 2 – Release 2

APPENDIX C

FIPS PUBS

Note: The specifications in HL7 SPL Standards will have precedence over FIPS PUBS

Table C-1 FIPS PUBS

FIPS No.	Title	Description
4-2	Representation of calendar date to facilitate interchange of data among information systems	This standard provides a means of representing calendar date to facilitate interchange of data among information systems. Adopts American National Standard Institute (ANSI) X3.30-1997: Representation of Date for Information Interchange (revision of ANSI X3.30-1985 [R1991]).
5-2	Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas - May 28, 1987	Provides a set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the U.S., and associated areas such as the Federated States of Micronesia and Marshall Islands, and the trust territory of Palau.
6-4	Counties and Equivalent Entities of the U.S., Its Possessions, and Associated Areas - Aug 31, 1990	Provides the names and three-digit codes that represent the counties and statistically equivalent entities of the 50 States, the District of Columbia, and the possessions and associated areas of the United States for use in the interchange of formatted machine-sensible data. Implements ANSI X3.31-1988.
8-6	Metropolitan Areas – Mar, 1995	Provides a four-digit numeric code for each metropolitan area in the U.S. and Puerto Rico, including units called Metropolitan Statistical Areas (MSAs), Consolidated Metropolitan Statistical Areas (CMSAs), and Primary Metropolitan Statistical Areas (PMSAs), and related units called New England County Metropolitan Areas (NECMAs). The general concept underlying MAs is that they are composed of a core area containing a large population nucleus together with adjacent communities having a high degree of economic and social integration with that core.
10-4	Countries, Dependencies, Areas of Special Sovereignty, and Their Principal Administrative Divisions – Apr, 1995	Provides a list of the basic geopolitical entities in the world, together with the principal administrative divisions that comprise each entity. Each basic geopolitical entity is represented by a two-character, alphabetic country code. Each principal administrative division is identified by a four-character code consisting of the two-character country code followed by a two-character administrative division code. These codes are intended for use in activities associated with the mission of the Department of State (DoS) and in National defense programs.
31	Guidelines for Automatic Data Processing Physical Security and Risk Management – June 1974	Provides guidance to Federal organizations in developing physical security and risk management programs for their Automated Data Processing (ADP) facilities. Can be used as a checklist for planning and evaluating security of computer systems.
46-3	Data Encryption Standard (DES) – 99 Oct 25	The selective application of technological and related procedural safeguards is an important responsibility of every Federal organization in providing adequate security to its electronic data systems. This publication specifies two cryptographic algorithms, the Data Encryption Standard (DES) and the Triple Data Encryption Algorithm (TDEA), which may be used by Federal organizations to protect sensitive data.

Table C-1 FIPS PUBS

FIPS No.	Title	Description
		Protection of data during transmission or while in storage may be necessary to maintain the confidentiality and integrity of the information represented by the data. The algorithms uniquely define the mathematical steps required to transform data into a cryptographic cipher and also to transform the cipher back to the original form. The DES is for use by Federal agencies within the context of a total security program consisting of physical security procedures, good information management practices, and computer system/network access controls. This revision supersedes FIPS 46-2 in its entirety.
73	Guidelines for Security of Computer Applications - June 30, 1980	Describes the different security objectives for a computer application, explains the control measures that can be used, and identifies the decisions that should be made at each stage in the life cycle of a sensitive computer application. For use in planning, developing, and operating computer systems which require protection.
83	Guideline on User Authentication Techniques for Computer Network Access Control - Sept 29, 1980	Provides guidance in the selection and implementation of techniques for authenticating the users of remote terminals in order to safeguard against unauthorized access to computers and computer networks.
102	Guideline for Computer Security Certification and Accreditation - Sept 27, 1983	Describes how to establish and how to carry out a certification and accreditation program for computer security. Certification consists of a technical evaluation of a sensitive system to see how well it meets its security requirements. Accreditation is the official management authorization for the operation of the system and is based on the certification process.
112	Password Usage - May 30, 1985	Defines 10 factors to be considered in the design, implementation, and use of access control systems that are based on passwords. It specifies minimum security criteria for such systems and provides guidance for selecting additional security criteria for password systems that must meet higher security requirements.
113	Computer Data Authentication - May 30, 1985	Specifies a Data Authentication Algorithm (DAA) which, when applied to computer data, automatically and accurately detects unauthorized modifications, both intentional and accidental. Based on FIPS PUB 46.
127-2	Database Language SQL (ANSI X3.135-1992) - June 02, 1993	FIPS 127-2 adopts ANSI X3.135-1992 Database Language (Structured Query Language [SQL]) that defines the syntactic and semantic rules for database definition and data manipulation in a relational model database management system.
161-2	Electronic Data Interchange (EDI) - May 22, 1996	FIPS 161-2 adopts, with specific conditions, the families of EDI standards known as X12, UN/EDIFACT, and HL7 developed by national and international standards developing organizations. FIPS 161-2 does not mandate the implementation of EDI systems within the federal government, but requires the use of the identified families of standards when federal agencies and organizations implement EDI systems.
181	Automated Password	Specifies a standard to be used by Federal organizations that

Table C-1 FIPS PUBS

FIPS No.	Title	Description
	Generator (APG) - Oct 05, 1993	require computer generated pronounceable passwords to authenticate the personal identity of an ADP system user, and to authorize access to system resources. The standard describes an automated password generation algorithm that randomly creates simple pronounceable syllables as passwords. The password generator accepts input from a random number generator based on the Data Encryption Standard (DES) cryptographic algorithm defined in FIPS 46-2.
186-2	Digital Signature Standard (DSS) - January 27, 2000	This standard specifies algorithms appropriate for applications requiring a digital, rather than written, signature. A digital signature is represented in a computer as a string of binary digits. A digital signature is computed using a set of rules and a set of parameters such that the identity of the signatory and integrity of the data can be verified. An algorithm provides the capability to generate and verify signatures. Signature generation makes use of a private key to generate a digital signature. Signature verification makes use of a public key, which corresponds to, but is not the same as, the private key. Each user possesses a private and public key pair. Private keys are kept secret; public keys may be shared. Anyone can verify the signature of a user by employing that user's public key. Only the user's private key can be used to generate a Signature. This revision supersedes FIPS 186-1 in its entirety.

APPENDIX D

Acronyms, Abbreviations, And Glossary of Terms

Table D-1. Acronyms and Abbreviations

Acronym/Abbreviation	Definition
ADIMS	Automated Drug Information Management System
ADP	Automated Data Processing
AHRQ	Agency for Healthcare Quality and Research
ANDA	Abbreviated New Drug Application
ANSI	American National Standards Institute
APG	Automated Password Generator
BLA	Biologics Licensing Application
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDR	Central Document Room
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CID	Center Ingredient Dictionary
CMSA	Consolidated Metropolitan Statistical Areas
COMIS	Center-wide Oracle Management Information System
COTS	Commercial Off-The-Shelf
CVM	Center for Veterinary Medicine
DAA	Data Authentication Algorithm
DARRTS	Document Archiving, Reporting, and Regulatory Tracking System
DDMAC	Division of Drug Marketing, Advertising, and Communications
DDR	Division Document Room
DES	Data Encryption Standard
DHHS	Department of Health and Human Services
DLR	Drug Listing Rule
DMETS	Division of Medication Errors and Technical Support
DoS	Department of State
DPRF	Drug Product Reference File
DRLS	Drug Registration and Listing System
DSRCS	Division of Surveillance, Research and Communication Support
EA	Enterprise Architecture
EDI	Electronic Data Interchange
EDR	Electronic Document Room
ELR	Electronic Labeling Rule
FDA	Food and Drug Administration
FIPS PUBS	Federal Information Processing Standards Publications
HL7	Health Level Seven
ICH	International Conference on Harmonisation
IMSC	Information Management Steering Committee
IND	Investigational New Drug Application
MaPPs	Manual of Policies and Procedures
MedWatch	Medical Products Reporting System
MSA	Metropolitan Statistical Area
NECMA	New England County Metropolitan Area
NCTR	National Center for Toxicological Research
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDC	National Drug Code

Table D-1. Acronyms and Abbreviations

Acronym/Abbreviation	Definition
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine
OC	Office of Commissioner
ODE	Online Data Entry
OIM	Office of Information Management
OIT	Office of Information Technology
OMB	Office of Management and Budget
OND	Office of New Drug
OPS	Office of Pharmaceutical Science
ORA	Office of Regulatory Affairs
OTC	Over-the-Counter
PDF	Portable Document Format
PDUFA	Prescription Drug User Fee Act
PLR	Professional Labeling Rule
PMRI	Patient Medical Record Information
PMSA	Primary Metropolitan Statistical Area
PPI	Patient Package Insert
SPL	Structured Product Labeling
SQL	Sequential Query Language
TBD	To Be Determined
TDEA	Triple Data Encryption Algorithm
TRB	Technical Review Board
TBD	To Be Determined
UNII	UNique Ingredient Identifier
XML	eXtensible Markup Language

Table D-2. Glossary of Terms

Term	Definition
Application	An initial request submitted to centers for approval of a new product (Biologics Licensing Application [BLA], New Drug Application [NDA], or Investigational New Drug Application [IND]).
Center for Biologics Evaluation and Research (CBER)	Center within FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.
Center for Devices and Radiological Health (CDRH)	Center responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products.
Center for Drug Evaluation and Research (CDER)	Center that assures that safe and effective drugs are available to the American people.
Center for Food Safety and Applied Nutrition (CFSAN)	Center responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.
Center for Veterinary Medicine (CVM)	Center that regulates the manufacture and distribution of food additives and drugs that will be given to animals.
Enterprise Architecture (EA)	A strategic information asset base that defines the business, the information necessary to operate the business, the technologies necessary to support the business operations, and the transitional processes necessary for implementing new technologies in response to the changing

Table D-2. Glossary of Terms

Term	Definition
	business needs.
Final SPL section	Refers to the approved SPL section after negotiation/review is over or CBE section prior to commencement of review activities.
National Center for Toxicological Research (NCTR)	Center that conducts peer-reviewed scientific research that supports and anticipates the FDA's current and future regulatory needs.
Structured Product Labeling (SPL) Standard	SPL Standard is an ANSI accredited XML document markup standard for product labeling.
Structured Product Labeling (SPL) Project	SPL Project is a part of larger initiative called the Daily Med. The project goal is to develop a technical environment that will support processing and managing labeling and listing to provide up to date product information. (make match intro definition)